5. 510(k) Summary

FEB 14 2013

EquaFlow™ Multivalve Infusion Catheter
510(k) Summary
21 CFR §807.92

1. Submitter Information:

Applicant:	Cook Incorporated
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Fax Number:	(812) 332-0281
Contact:	Amber Brown
Contact Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Email	amber.brown@cookmedical.com
Contact Phone Number:	812-339-2235 Ext. 2234
Contact Fax Number:	812-332-0281

2. Device Information:

Trade name:	EquaFlow™ Multivalve Infusion Catheter
Common name:	Continuous flush catheter
Classification:	Class II
Regulation:	21 CFR 870.1210
Product Code:	KRA

3. Predicate Device:

The EquaFlow Multivalve Infusion Catheter is substantially equivalent to the Cragg-McNamara™ Valved Infusion Catheters, manufactured by Micro Therapeutics Incorporated, which are cleared under 510(k) number K964868. The EquaFlow Multivalve Infusion Catheter is also substantially equivalent to the Pulse*Spray® Infusion System, manufactured by AngioDynamics Incorporated, which is cleared under 510(k) number K961763.

4. Comparison to Predicates:

The proposed device is substantially equivalent to the predicates in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, anatomical location, and method of sterilization. The proposed devices will be manufactured

according to Cook Incorporated's specified process controls, sterilization, and packaging procedures.

5. Device Description:

The EquaFlow Multivalve Infusion Catheter (MIC) is manufactured as a 4.0 or 5.0 French catheter, available in lengths of 40, 65, 100, or 130 centimeters (cm). The EquaFlow Multivalve Infusion Catheter is manufactured with distal and proximal platinum/iridium radiopaque markers indicating the location of the side-valves' infusion segment. The infusion segments are in lengths of 5, 10, 15, 20, 30, 40, 50, and 60 cm. The number of side-valves is directly related to the length of the infusion segment, with holes 0.10 inches apart at the distal end and 0.25 inches apart as you move toward the proximal end. The distal tip of the EquaFlow Multivalve Infusion Catheter is straight and tapered. The catheter is manufactured with a nylon hub and strain relief at the proximal end.

6. Intended Use:

The EquaFlow Multivalve Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents into the general vasculature. It is not intended for coronary, pediatric or neonatal use.

7. Technological Characteristics:

The proposed device is substantially equivalent to the predicates in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, anatomical location, and method of sterilization.

The EquaFlow Multivalve Infusion Catheter is a single lumen catheter intended for delivering controlled infusions of intravascular therapeutic solutions. The catheter tip is designed with a tip valve, which allows occlusion of the catheter end hole without the use of a wire guide. The EquaFlow Multivalve Infusion Catheter is designed with side-valves spiraling along the specified infusion segment length of the distal portion of the catheter, providing a more even distribution of therapeutic solutions to the targeted location.

The proposed EquaFlow Multivalve Infusion Catheter was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Tensile
- Flow Restriction
- Flow Rate
- Burst Pressure
- Liquid/Air Leakage
- Biocompatibility

The results of these tests support a conclusion that the proposed Equaflow Multivalve Infusion Catheter and the predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 14 2013

Cook Incorporated
Amber Brown, Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K123235
Trade/Device Name: EquaFlow Multivalve Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: January 11, 2013
Received: January 14, 2013

Dear Ms. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K123235

Device Name: EquaFlow™ Multivalve Infusion Catheter

Intended Use:

The EquaFlow™ Multivalve Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents into the general vasculature. It is not intended for coronary, pediatric or neonatal use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123235